DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 4 2000

Dr. Heather Anderson
Regulatory Affairs
Randox Laboratories, Ltd.
Ardmore, Diamond Road,
Crumlin, Co. Antrim,
United Kingdom,
BT29 4QY

Re: K001009
Trade Name: CRP (highsensitivity assay)
Regulatory Class: II
Product Code: DCK
Dated: July 7, 2000
Received: July 10, 2000

Dear Dr. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~NOT KNOWN~~ K001009

Device Name: CRP (highsensitivity assay)

Indications For Use :

The Randox Laboratories Ltd. High Sensitivity CRP Test Kit is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein in serum . The method is an immunoturbidimetric assay in which the sample is reacted with a buffer and anti-CRP coated latex. The formation of an antigen-antibody complex results in an increase in turbidity, the extent of which is measured as the absorbance at 550nm. By constructing a standard curve from the absorbances of standards, the CRP concentration of the sample can be determined. The measurement of C-reactive protein levels in serum is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Increased levels of C-reactive protein are observed in acute phase response.

This Application Sheet has been developed for the Hitachi 717 Analyser and must be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001009

Prescription Use ✓ OR **Over-The-Counter Use**_____
(Per 21 CFR 801.109) (Optional format 1-2-96)